REMARKS

Claims 6-11 and 13-17 are pending in this application. Claims 6 and 11 have been amended. No new matter has been added. Claims 1-5, 12 and 18-24 have been canceled without prejudice or disclaimer. Applicants, by canceling any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Presently pending independent claim 6 has been amended to recite "a pharmaceutical composition comprising the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or a solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, in fixed combination and in an administration form suitable for inhalative administration by means of a powder inhaler, wherein the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, are present ready mixed in a fixed combination." Support for claim 6 as amended can be found throughout the specification and the claims as originally filed, for example page 5 of the present specification. Claims 7-10 depend, either directly or indirectly, from claim 6.

Presently pending independent claim 11 has been amended to recite "a method of treating an airway disease in a patient comprising administering to a patient in need

thereof a therapeutically effective amount of the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof in fixed combination and in an administration form suitable for inhalative administration by means of a powder inhaler with the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, wherein the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, are present ready mixed in a fixed combination." Support for claim 11 as amended can be found throughout the specification and the claims as originally filed, for example page 5 of the present specification. Claims 13-17 depend, either directly or indirectly, from claim 11.

In view of the remarks set forth below, further and favorable consideration is respectfully requested.

I. At pages 5-8 of the Official Action, claims 6-11 and 13-17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Magee et al. (U.S. Patent Application Publication No. 2002/0111495) in view of Calatayud et al. (U.S. Patent No. 5,482,934).

The Examiner asserts that it would have been obvious to a person of ordinary skill in the art to incorporate the R-epimer of ciclesonide, as described in Calatayud et al. into the composition comprising compounds of formula I, ciclesonide and formoterol, as described in Magee et al. to arrive at the presently claimed subject matter.

In view of the following, Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U. S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

It is submitted that a proper case of *prima facie* obviousness has not been established because, whether taken alone or together, none of the cited references teach or suggest all the limitations of the claims as required by *In re Wilson*.

Independent claim 6 is directed to a pharmaceutical composition comprising the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or a solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, in fixed combination and in an administration form suitable for inhalative administration by means of a powder inhaler, wherein the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, are present ready mixed in a fixed combination. Claims 7-10 each depend, either directly or indirectly, from claim 6.

Independent claim 11 is directed to a method of treating an airway disease in a patient comprising administering to a patient in need thereof a therapeutically effective amount of the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof in fixed combination and in an administration form suitable for inhalative administration by means of a powder inhaler with the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, wherein the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, are present ready mixed in a fixed combination. Claims 13-17 depend, either directly or indirectly, from claim 11.

In contrast, Magee et al. describe the use of a compound selected from a general class of PDE4 inhibitors used in combination with other therapeutic agents, including formoterol and ciclesonide. Accordingly, Magee et al. require the combination of a PDE4 inhibitor with an additional active agent such as ciclesonide or formoterol. Nowhere does Magee et al. describe the use of R,R-formoterol. As such, it does not disclose a combination of ciclesonide and R,R-formoterol, present ready mixed in a fixed combination, as presently claimed.

In further contrast, Calatayud et al. describes the synthesis of a general class of steroids that read on the structure of ciclesonide. Calatayud et al. also describes the purification of the mixture of epimers to obtain either of the epimers in a proportion of at least 99.9%. Accordingly, whether taken alone or in combination, none of Magee et al. and Calatayud et al. teach or suggest ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof in fixed combination and in an administration form suitable for inhalative administration by means of a powder inhaler with the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, wherein the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, are present ready mixed in a fixed combination, as presently claimed. Accordingly, Applicants respectfully submit that a proper case of *prima facie* obviousness has not been established because, whether taken alone or together, none of the cited references teach or suggest all the limitations of the claims as required by *In re Wilson*.

As such, the Examiner has failed to demonstrate a *prima facie* case of obviousness against pending claims 6-11 and 13-17. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

II. At pages 8-11 of the Official Action, claims 6-11 and 13-17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Keller et al. (U.S. Patent No. 6,645,466) in view of Magee et al. and in further view of Calatayud et al.

The Examiner asserts that Keller et al. describe dry powder formulations for inhalation containing a pharmaceutically effective carrier, pharmaceutically active compounds and magnesium stearate. The Examiner also asserts that it would have been obvious to one of ordinary skill in the art to substitute the R-epimer of ciclesonide as described in Calatayud et al. into the compositions of Keller et al., and to use the resultant compositions for the treatment of airway diseases as described in Magee et al. to arrive at the presently claimed subject matter.

Applicants respectfully traverse this rejection because a *prima facie* case of obviousness has not been established.

A brief outline of relevant authority is set forth above in Section I.

It is submitted that a proper case of *prima facie* obviousness has not been established because, whether taken alone or together, none of the cited references teach or suggest all the limitations of the claims as required by *In re Wilson*.

Independent claim 6 is directed to a pharmaceutical composition comprising the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or a solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, in

fixed combination and in an administration form suitable for inhalative administration by means of a powder inhaler, wherein the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, are present ready mixed in a fixed combination. Claims 7-10 each depend, either directly or indirectly, from claim 6.

Independent claim 11 is directed to a method of treating an airway disease in a patient comprising administering to a patient in need thereof a therapeutically effective amount of the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof in fixed combination and in an administration form suitable for inhalative administration by means of a powder inhaler with the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, wherein the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, are present ready mixed in a fixed combination. Claims 13-17 depend, either directly or indirectly, from claim 11.

As discussed above in Section I, none of Magee et al. and Calatayud et al., whether taken alone or in combination, teach or suggest all the limitations of the claims as required by *In re Wilson*.

Keller et al. do not remedy the deficiencies of Magee et al. and Calatayud et al. Keller et al. is directed to dry powder formulations for inhalation which contain a

pharmaceutically ineffective carrier of non-inhalable particle size and a finely divided pharmaceutically active compound of inhalable particle size. *See* Keller et al. at the Abstract. According to Keller et al., magnesium stearate is used in the dry powder formulations. *Id.* However, like Magee et al. and Calatayud et al., Keller et al. do not teach or suggest ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof in fixed combination and in an administration form suitable for inhalative administration by means of a powder inhaler with the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, wherein the active compound ciclesonide or a solvate, epimer, physiologically functional derivative or solvate of a physiologically functional derivative thereof and the active compound R,R-formoterol or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof, are present ready mixed in a fixed combination. Nothing in Keller et al., Magee et al. and Calatayud et al. describe the use of R,R-formoterol. As such, none of Keller et al., Magee et al. and Calatayud et al. describe a combination of ciclesonide and R,R-formoterol, present ready mixed in a fixed combination, as presently claimed. Accordingly, Applicants respectfully submit that a proper case of *prima facie* obviousness has not been established because, whether taken alone or together, none of the cited references teach or suggest all the limitations of the claims as required by *In re Wilson*.

As such, the Examiner has failed to demonstrate a *prima facie* case of obviousness against pending claims 6-11 and 13-17. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

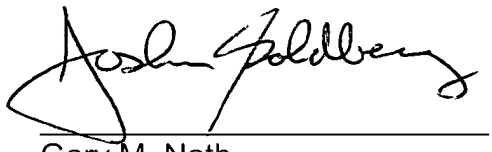
CONCLUSION

The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



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